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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/390,846	09/14/1999	JACOBUS JOHANNES KOK	I/95150-US/D	7646

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EXAMINER	
FIELDS, IESHA P	
ART UNIT	PAPER NUMBER
1645	

DATE MAILED: 07/23/2002

14

Please find below and/or attached an Office communication concerning this application or proceeding.

File Copy

Office Action Summary

Application No.	Applicant(s)
09/390,846	Kok et al
Examiner	**Art Unit**
I sha P. Fileds	1645

-- The MAILING DATE of this communication appears on th cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1) ☒ Responsive to communication(s) filed on 3/22/02

2a) ☐ This action is **FINAL.** 2b) ☒ This action is non-final.

3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

4) ☒ Claim(s) 1-3, 11, 13-25 is/are pending in the applica

4a) Of the above, claim(s) 14, 15, 21, 22, 25 is/are withdrawn from considera

5) ☐ Claim(s) _____ is/are allowed.

6) ☒ Claim(s) 1-3, 11, 16-20, 23, 24 is/are rejected.

7) ☐ Claim(s) _____ is/are objected to.

8) ☐ Claims _____ are subject to restriction and/or election requirem

Application Papers

9) ☐ The specification is objected to by the Examiner.

10) ☐ The drawing(s) filed on _____ is/are a) ☐ accepted or b) ☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13) ☒ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a) ☐ All b) ☐ Some* c) ☒ None of:

1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

*See the attached detailed Office action for a list of the certified copies not received.

14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

a) ☐ The translation of the foreign language provisional application has been received.

15) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☒ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s). _____
4) ☐ Interview Summary (PTO-413) Paper No(s). _____
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other:

1. The examiner acknowledges the amendment and notice of appeal filed 3/26/02. The after final amendment will be entered. Upon further consideration by the examiner, the finality of the last office action is withdrawn.

2. Claims 1-3, 11, 13-25 are pending. Claims 14, 15, 21, 22 and 25 have been withdrawn from consideration. Claims under consideration in this office action are claims 1-3, 11, 16-20, 23 and 24.

3. The examiner acknowledges applicant's claim for foreign priority, however, the foreign priority document has not been received. Therefore the priority date afforded the claims under consideration in this application is the date of filing of the instant application, which is 9/14/99.

4. The figures are objected to for reasons set forth in the accompanying PTO form 948. Appropriate correction is required.

5. Upon further consideration by the examiner and in view of applicant's arguments, the rejection of claims under 35 USC 102(b) as anticipated by Binger et al is withdrawn.

NEW GROUNDS OF REJECTION

Claim Rejections - 35 USC § 112

6. Claims 1-3, 11, 16-20, 23 and 24 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for an isolated 37kd protein from Eimeria acervulina consisting of the amino acid sequence set forth in seq. I.D. No. 2 and a vaccine

comprising the 37kd protein, does not reasonably provide enablement for any fragment of the isolated protein. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

The claims are broadly drawn to an isolated protein, fragments, biological variants and equivalents of the protein for use in a vaccine composition. The specification does not enable all variants and equivalents of the claimed protein. The scope of the claims is not commensurate with the enablement provided by the disclosure with regard to the extremely large number of proteins broadly encompassed by the claims and the claims broadly encompass a significant number of inoperative species. Since the amino acid sequence of a protein determines its structural and functional properties, predictability of which changes can be tolerated in a protein's amino acid sequence and still retain similar activity requires a knowledge of and guidance with regard to which amino acids in the protein's sequence, if any, are tolerant of modification and which are conserved (i.e. expectedly intolerant to modification), and detailed knowledge of the ways in which the proteins' structure relates to its function. However, the problem of predicting protein structure from mere sequence data of a single protein and in turn utilizing predicted structural determinations to ascertain functional aspects of the protein and finally what changes can be tolerated with respect thereto is extremely complex and well outside the realm of routine experimentation.

While recombinant and mutagenesis techniques are known, it is **not** routine in the art to screen for multiple substitutions or multiple modifications of other types and the positions within the protein's sequence where amino acid modifications can be made with a reasonable expectation of success in obtaining similar activity are limited in any protein and the result of such modifications is unpredictable based on the instant disclosure. One skilled in the art would expect any tolerance to modification shown for a given protein to diminish with each further and additional modification, e.g. multiple substitutions. The sequence of some proteins is highly conserved and one skilled in the art would not expect tolerance to any amino acids modification in such proteins.

The specification does not support the broad scope of the claims which encompass all modifications and fragments because the specification does **not** disclose the following :

- the general tolerance to modification and extent of such tolerance;

- specific positions and regions of the sequence(s) which can be predictably modified and which regions are critical;

- what fragments, if any, can be made which retain the biological activity of the intact protein; and

- the specification provide essentially no guidance as to which of the essentially infinite possible choices is likely to be successful.

Thus, applicants have **not** provided sufficient guidance to enable one of ordinary skill in the art to make and use the claimed protein in manner reasonably correlated with the scope of the claims broadly including any number of additions, deletions or substitutions and fragments of any size. The scope of the claims must bear a reasonable correlation with the scope of enablement (In re Fisher, 166 USPQ 19 24 (CCPA 1970)). Without such guidance, the changes which can be made

in the proteins structure and still maintain activity is unpredictable and the experimentation left to those skilled in the art is unnecessarily, and improperly, extensive and undue. See Amgen, Inc. v. Chugai Pharmaceutical Co. Ltd., 927 F.2d 1200, 18 USPQ2d 1016 (Fed. Cir. 1991) at 18 USPQ2d 1026-1027 and Ex parte Forman, 230 U.S.P.Q. 546 (Bd. Pat. App. & Int. 1986). In view of all of the above it is determine that it would require undue experimentation of one of skill in the art to make and use the invention commensurate in scope with the claimed subject matter.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless -
>
> (e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371© of this title before the invention thereof by the applicant for patent.

The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) do not apply to the examination of this application as the application being examined was not (1) filed on or after November 29, 2000, or (2) voluntarily published under 35 U.S.C. 122(b). Therefore, this application is examined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

7. Claims 1-3, 11, 16-20, 23 and 24 are rejected under 35 U.S.C. 102(e) as being anticipated by Kok et al, U.S. Pat. No. 6,100,241. It should be noted that this rejection is being set forth because the foreign priority document has not been received as stated previously.

The claims are drawn to an isolated protein, fragments, variants and equivalents of eimeria lactate dehydrogenase and vaccines for the protection of poultry against infection from eimeria. Kok et al teach Eimeria proteins possessing lactate dehydrogenase activity. Kok et al also teach vaccines comprising the eimeria proteins in combination with adjuvants and/or carriers (abstract, columns 4-6, 13-16). The proteins and vaccines of Kok et al are the same as the claimed proteins and vaccines. Since the Office does not have the facilities for examining and comparing applicants' protein and vaccine with the protein and vaccine of the prior art, the burden is on applicant to show a novel or unobvious difference between the claimed product and the product of the prior art (i.e., that the protein and vaccine of the prior art does not possess the same material structural and functional characteristics of the claimed protein and vaccine). See In re Best, 562 F.2d 1252, 195 USPQ 430 (CCPA 1977) and In re Fitzgerald et al., 205 USPQ 594.

8. Claims 1-3, 11, 16-20, 23 and 24 are rejected under 35 U.S.C. 102(e) as being anticipated by Binger et al, U.S. Pat. No. 5,661,015. The claims are drawn to an isolated protein, fragments, variants and equivalents of eimeria lactate dehydrogenase and vaccines for the protection of poultry against infection from eimeria. Binger et al teach the isolation of proteins comprising antigenic and/or immunoreactive determinants of Eimeria antigens with an apparent molecular weight of 37kd (column 4, lines 45-68). Binger et al also teach fragments of these proteins which fragments and proteins can be formulated into vaccines (column 17, lines 7-68). The fragments of Binger et al are the same as the claimed biologically active variants or active parts of the variants.

Characteristics such as immunoreactivity with antiserum raised against seq. I.D. No.2 and effective amount of the fragments would be inherent in the in the vaccines of the prior art. Additionally, it should be noted that Binger et al do not specifically teach that the protein and fragments can be isolated from the Eimeria intracellularly. However, while the proteins of the reference were not found intracellularly, they nevertheless appear to be the same as the proteins and fragments broadly and non-specifically claimed by applicants because they appear to possess the same or similar functional characteristics, i.e. LDH activity and molecular weight of 37kd. The source of a particular protein does not impart novelty or unobviousness to a particular protein when said protein is taught by the prior art. Since the Patent Office does not have the facilities for examining and comparing applicants' proteins with the proteins of the prior art reference, the burden is upon applicants to show an unobvious distinction between the material structural and functional characteristics of the claimed proteins and the proteins of the prior art. See In re Best, 562 F.2d 1252, 195 USPQ 430 (CCPA 1977) and In re Fitzgerald et al., 205 USPQ 594.

Although the reference appears to disclose the same purified proteins claimed by applicants, the reference does not disclose the proteins **produced** or found intracellularly. However, the purification or production of a protein by a particular process or from a particular source does not impart novelty or unobviousness to a protein when the same protein is taught by the prior art. This is particularly true when the properties of the protein are not changed by the process in an unexpected manner. See In re Thorpe, 227 USPQ 964 (CAFC 1985); In re

Marosi, 218 USPQ 289, 292-293 (CAFC 1983); In re Brown, 173 USPQ 685 (CCPA 1972). Therefore, even if a particular **process** used to prepare a protein or source is novel and unobvious over the prior art, the protein per se, even when limited to the particular process, is unpatentable over the same protein taught by the prior art. See In re King, 107 F.2d 618, 620, 43 U.S.P.Q. 400, 402 (C.C.P.A. 1939); In re Merz, 97 F.2d 599, 601, 38 U.S.P.Q. 143, 144-45 (C.C.P.A. 1938); In re Bergy, 563 F.2d 1031, 1035, 195 U.S.P.Q. 344, 348 (C.C.P.A. 1977) vacated 438 U.S. 902 (1978); and United States v. Ciba-Geigy Corp., 508 F. Supp. 1157, 1171, 211 U.S.P.Q. 529, 543 (D.N.J. 1979).

9. Any inquiry concerning this communication or earlier communications from the examiner chould be directed to Examiner Iesha P. Fields whose telephone number is 703-605-1208. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Lynette R. F. Smith, can be reached on 703-308-3909. Any inquiry of a general nature or relating to the status of this application or proceeding should be ddirected to the receptionist whose telephone number is 703-308-0196.

Iesha P. Fields/iep
July 18, 2002

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